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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/897,295	06/29/2001	William J. Boyle	ACS-56001 (26361)	1994

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EXAMINER

MITCHELL, TEENA KAY

ART UNIT PAPER NUMBER

3743

DATE MAILED: 09/29/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/897,295

Applicant(s)

BOYLE ET AL.

Examiner

Teena Mitchell

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 May 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 3-32 and 41-51 is/are pending in the application.
- 4a) Of the above claim(s) 14-19 and 27-32 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 3-13, 20-26 and 41-51 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____

DETAILED ACTION

Response to Arguments

Applicant's arguments, see page 8, filed 5/25/05, with respect to 112, first paragraph have been fully considered and are persuasive. The 112 first paragraph rejection of claims 43 and 51 has been withdrawn.

Applicant's arguments filed 5/25/05 have been fully considered but they are not persuasive. Applicant argues that Amplatz tubular braid prevents any expansion; however, the reference of Amplatz teaches that "...the pitch of wire stands (i.e., the angle defined between the turns of the wire and the axis of the braid) and the pick of the fabric (i.e. the number of turns per unit length) may be adjusted as desired for a particular application. As such is taught by Amplatz one of ordinary skill in the art would based on the pitch and the pick of the fabric select such to provide expansion of the expandable housing. Furthermore, in order to provide additional support for the examiners rejection, the teachings of Kelley is provided in the rejection. Applicant argues that Amplatz teaches away from expansion but does not provide any reference to such in the Amplatz references. The braids provide flexibility (i.e., the ability to expand) to the tubular member, while providing reinforcement.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 3-13, 20-26, 41, 42, and 44-41 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The specification provides support for the limitation of, "...does not interfere with the radial expansion of the housing portion..." however applicant is claiming "...the expansion of the housing portion...".

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 3-13, 20-26, and 41-51 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hopkins et.al. (6,544,279) in view of Amplatz (6,123,715) and Kelley (6,517,765).

Hopkins in a restraining device discloses a restraining sheath having an expandable housing portion (594) adapted to receive and maintain the self-expanding medical device (588) in a collapsed condition on the delivery device, the expandable

housing portion being adapted to expand between a contracted position (Fig. 23A) and an expanded position (Fig. 23B), the housing portion having sufficient column strength to maintain the self-expanding medical device (588) in its collapsed condition on its delivery device, wherein the expandable housing portion (594) is made primarily from an elastic material which is stretchable between the contracted position and expanded position.

The difference between Hopkins and claim 3 is a reinforcing member associated therewith which provides additional column strength to the housing portion but does not interfere with the expansion of the housing portion.

Amplatz in an intravascular occlusion device teaches the use of tubular braids in medical devices providing reinforcing means to the wall of a guiding catheter, which may be adjusted as desired for a particular application by the pitch and pick of the fabric (Col. 3, lines 39-57). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the expandable housing portion of Hopkins to employ any well-known tubular braids doing so would have provided a means to reinforce the expandable housing portion. Further the teachings of Kelley teach the use of braids in varying braid pick counts vary the flexibility of the tubing (Col. 1, lines 40-67 and Col. 2, lines 1-15). Based on a standard dictionary definition of "flexible, Capable of being bent or flexed: Pliable. "pliable" meaning, easily bent or shaped: Malleable, capable of being shaped or formed. Therefore, based on the teachings of braids of Kelley, the tubular braids of Amplatz could be adjusted to allow for expansion of the

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housing portion and therefore, would not interfere with the expansion of the housing portion, as one of ordinary skill in the art would know.

With respect to claim 4, Amplatz does not teach a plurality of reinforcing members. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have a plurality of reinforcing members, since it has been held that mere duplication of the essential working parts of a device involves only routine skill in the art. *In re Harza*, 274 F.2d 669, 124 USPQ 378 (CCPA 1960).

With respect to claim 5, Amplatz does not teach the reinforcing member extending substantially along the length of the expandable housing portion. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have the reinforcing member extending substantially along the length of the expandable housing portion, since it has been held that rearranging parts of an invention involves only routine skill in the art and applicant has not disclosed that having the reinforcing members extending substantially along the length of the expandable housing portion provides an advantage or solves a particular problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with the reinforcing member positioned in any other arrangement of the housing portion because the housing portion would still be expandable. Therefore, it would have been an obvious matter of design consideration to modify Hopkin/Amplatz to obtain the invention as specified in claim 5.

With respect to claim 6, Amplatz teaches the reinforcing members are elongated bar-like members made from a material having a high stiffness (Col. 4, lines 11-65).

With respect to claim 7, Hopkins does not specifically disclose the elastic material selected from the group of materials which includes silicone, polyurethane, polyisoprene, and lower durometer PEBAX. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have the elastic material selected from the group of materials which includes silicone, polyurethane, polyisoprene, and lower durometer PEBAX, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of design consideration. Applicant has not disclosed that having the elastic member selected from the group of materials which includes silicone, polyurethane, polyisoprene, and lower durometer PEBAX provides an advantage, is used for a particular purpose, or solves any stated problem. One of ordinary skill in the art, furthermore would have expected Applicant's invention to perform equally well with other materials which provide elastic properties because the housing portion would still be able to expand. Therefore, it would have been an obvious matter of design consideration to modify Hopkins/Amplatz to obtain the invention as specified in claim 7.

With respect to claim 8, note rejection of claim 7 above.

With respect to claim 9, Hopkins/Amplatz do not disclose/teach the reinforcing members loaded with a material having high radiopacity. However, Hopkins does disclose the use of radiopaque bands (596, 598) providing a means so that positions of the bands relative to one another may be accurately determined. It would have been obvious to one of ordinary skill in the art to provide the reinforcing members with a

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material having high radiopacity doing so would have provided a means to locate the reinforcing members relative to other structures while in use as disclosed by Hopkins and the use of radiopaque bands.

With respect to claim 10, note rejection of claim 7 above.

With respect to claims 11-13, note rejection of claim 5 above.

With respect to claim 20, Hopkins discloses an expandable housing portion (594) that includes a low expansion section with at least one expansion member (590) disposed within the low expansion section to provide the elasticity needed to move the housing portion between the contracted position and expanded position. ("low expansion section" is being considered by the examiner as a relative phrase which the specification does not clearly define as to what constitutes a "low expansion section"). Also based on the teachings of Amplatz and the pitch and pick of the braid being adjusted as desired for a particular application it would have been obvious to one of ordinary skill in the art to have low expansion sections.

With respect to claim 21, note rejection of claim 4 above.

With respect to claim 22, note rejection of claim 9 above.

With respect to claims 23 and 24, note rejection of claim 7 above.

With respect to claim 25, note rejection of claim 4 above.

With respect to claim 26, Amplatz teaches reinforcing members (Col. 3, lines 39-57) which are fully capable of preventing the low expansion sections from tearing as the expandable housing portion expands from the contracted position to the expanded

position because the reinforcing members provide strength which allowing for expansion.

With respect to claim 41, note rejection of claim 1 above.

With respect to claim 42, note rejection of claim 4 above.

With respect to claims 43, 49, and 50, note rejection of claim 5 above.

With respect to claim 44, note rejection of claim 6 above.

With respect to claims 45, 46, and 48, note rejection of claim 7 above.

With respect to claim 47, note rejection of claim 9 above.

With respect to claim 51, the reinforcing members of Amplatz are fully capable of helping to bias the expandable housing portion in the contracted position based on the pitch and pick used.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

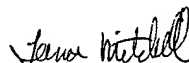
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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Teena Mitchell whose telephone number is (571) 272-4798. The examiner can normally be reached on Monday-Friday however the examiner is on a flexible schedule.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry Bennett can be reached on (571) 272-4791. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Teena Mitchell
Primary Examiner
Art Unit 3743
September 24, 2005

TKM
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